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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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01/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSC@faegre.com

Office Action Summary	Application No. 10/821,421	Applicant(s) OSPYKA, PETER	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,21-31,33-45 and 48-65 is/are pending in the application.
- 4a) Of the above claim(s) 23,26-30 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,21,22,24,25,31,33-45 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/16/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 18, 19, 21, 22, 24, 25, 31, 33-45 and 48-50 have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendments.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/16/2008 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. However, should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a certified English translation of the foreign application must be submitted in reply to this action. See MPEP § 201.15. Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

5. Until the foreign priority has been perfected, a rejection in view of Shiroff et al. (US 7,418,298) would be considered proper.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 18, 19, 21, 22, 24, 25, 31, 33-45 and 48-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 23 and 25 of copending Application No. 10/971,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 18, 19, 21, 22, 24, 25, 31, 33-45 and 48-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US Patent No. 7,418,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many

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others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

9. Claims 18, 19, 21, 22, 24, 25, 31, 33-45 and 48-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/972,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 18, 22, 43, 44 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Abrams (US 5,492,119). Abrams discloses an apparatus with an anchor

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49 configured to initially advance through myocardial tissue in a straight configuration, and to anchor in cardiac tissue in a second, J-shaped configuration 39 (Col. 4, lines 63-67). A tension element 35 has a proximal end and a distal end, the distal end being attached to the anchor 39 (see figure 2). An electrode 27 has an inner guide channel 31 that accommodates the tension element, thus loosely coupling the tension element and anchor to the electrode. The electrode has a pole 29 at the distal end for stimulating the myocardium (Col. 6, lines 7-18). Since the tension element and the electrode are not attached, it is the Examiner's position that the electrode may inherently be threaded over the proximal end of the tension element and slideably advanced along the tension element. As seen in figures 3 and 4, the guide channel has a proximal end that allows the tension element to exit therethrough.

12. Regarding claim 44, Abrams discloses a tool 37 for inserting the anchor.

13. Claims 18, 22, 33, 36, 43, 44 and 50 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Hine et al. (US 2003/0204231, hereinafter Hine). Hine discloses an apparatus with an anchor 204 configured to advance to myocardial tissue in a first orientation, and then anchor against an epicardial surface in a second orientation (par. 0029). A tension element 202 is attached to the anchor at a distal end, while an electrode 300 with an inner guide channel is threaded over the proximal end of the tension element and advanced towards the anchor during implantation, where it is then attached in order to secure the electrode in the heart (see figure 4 and par. 0030). The electrode has a pole 308 at the distal end for stimulating the myocardium, as well as a

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proximal opening that allows the proximal end of the tension element to exit therethrough.

14. Regarding claims 33 and 36, the proximal opening of the inner guide channel is considered a connection point because that is where the tension element and the electrode come together. By threading the tension element through this opening, the tension element can attach to the electrode at the distal end.

15. Regarding claim 44, Hine discloses a tool 200 for inserting the anchor that is detachably coupled to the anchor at an attachment area.

16. Claims 18, 19, 21, 22, 24, 25, 31, 33-38, 43-45, 48 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Shiroff et al. (US 7,418,298, hereinafter Shiroff). Shiroff discloses an apparatus for inserting an electrode into a myocardium of the heart (see figure 1). Shiroff discloses an anchor 72 configured to advance through myocardial tissue in a first orientation inside a tool and to anchor against an epicardial surface in a second orientation (see App. No. 10/971,551, incorporated by reference in Col. 1, lines 34-35 and Col. 4, lines 30-33). Attached to the anchor is a tension element 70' (see figure 6). An electrode 10 with an inner guide channel is threaded over the proximal end of the tension element and advanced towards the anchor during implantation, where it is then attached in order to secure the electrode in the heart (see App. No. 10/971,551, incorporated by reference in Col. 1, lines 34-35 and Col. 4, lines 30-33). The electrode has a pole 40a', 50', 40b' at the distal end for stimulating the myocardium, as well as a proximal opening that allows the proximal end of the tension element to exit therethrough. The anchor and the tension element connect to

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the distal end of the electrode with a locking arrangement (see App. No. 10/971,577, incorporated by reference in Col. 1, lines 30-33 and Col. 5, lines 25-31).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 38 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hine in view of Official Notice. Hine, as described above, discloses the applicant's basic invention with the exception of the electrode including an anode spaced apart from a cathode. However, the use of unipolar and bipolar electrodes and pacing is notoriously old and well known in the art as being interchangeable configurations for stimulating muscle tissue. One of ordinary skill in the art would have found it obvious to modify the pole to include both an anode and a cathode to allow for bipolar pacing, especially since this allows for charge balancing, which results in less pain felt by the patient.

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20. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hine in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey). Hine, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart.

Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Hine by utilizing two leads extending from a common supply as taught by Wesbey in order to stimulate two locations of a muscle at the same time.

21. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiroff in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey). Shiroff, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart.

Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Shiroff by utilizing two leads extending from a common supply as taught by Wesbey in order to stimulate two locations of a muscle at the same time.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. D. B./
Examiner, Art Unit 3766

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
January 14, 2009